

UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/192,798 11/24/98 LICHEN

E LIC-10002/03

EXAMINER
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HM12/1223

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ART UNIT	PAPER NUMBER
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1614

DATE MAILED:

12/23/99

*Restriction*

*Requirements*

*Doc 1-23-00*

*\* Mark 16-23-00*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



# Office Action Summary

Application No.  
09/198,798

Applicant(s)  
Lichten

Examiner  
Frederick Krass

Group Art Unit  
1614



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-50 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-50 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

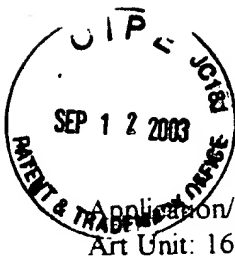
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —



Filed  
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Application/Control Number: 09/198,798  
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### Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14 and 30-43, drawn to methods of treating diabetes, classified in class 514, subclass 169 plus.
- II. Claims 15-29, drawn to testosterone assays, classified in class 436, subclass 86 plus.

The inventions are distinct, each from the other because:

Inventions II and I are processes related in a manner analogous to that which exists with mutually exclusive species in an intermediate-final product relationship; accordingly, the same reasoning applies. Distinctness is proven for claims in this relationship if the intermediate is useful separately (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate comprises a process for performing a testosterone test (see claim 25), which is plainly useful for medical procedures unrelated to the treatment of diabetes, and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claims 44-50 link inventions I and II and will be examined with the elected group.

### Election of Species Requirement

If group I is elected in response to the restriction requirement set forth above, a further election of species requirement will be imposed as follows:

This application contains claims directed to the following patentably distinct species of the claimed invention: administrative methods (intramuscular, subcutaneous, by pellet, by transdermal gel, etc).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The claimed subject matter is extremely complex, from both a legal and factual standpoint. Accordingly, this requirement has been written out to give applicant sufficient time to make an informed, well-considered decision.

#### Correspondence

Any inquiry concerning this communication or earlier communications regarding the substantive aspects of the communication (the action *per se*, questions regarding patentability, etc) from the examiner should be directed to Frederick Krass whose telephone number is (703) 308-4335. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

The examiner generally returns his phone calls in a very prompt manner. If attempts to reach the examiner by telephone are unsuccessful (allowing for a few days in case the examiner is on sick leave), the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Frederick Krass  
Primary Examiner  
Art Unit 1614

